

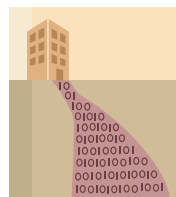


Data Sharing: Taking Research Further

February 6-7 2012 – NIEHS Workshop: Data Sharing Strategies for Environmental Health Science Research, Durham, North Carolina

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Human Services (HHS)



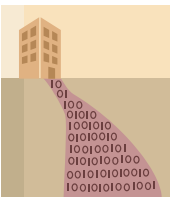
Data Sharing: Taking Research Further

Non-Sharing

- Duplicative funding to recreate same data/resources
 - Less funding for other original research
 - Revalidate new resources, slows research
- Block/Impede research (e.g., patent suits against researchers)
 - People block research when using patents inappropriately

Sharing

- Helps research dollars go further
- Allows more funding to go to more original research
- Promotes faster research advances (no need to recreate resources) and comparable research results
- Provides synergies-Whole is greater than sum of its parts

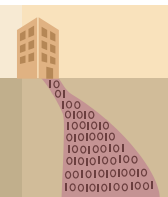


NIH Sharing Policies

- NIH Sharing Policies and Related Guidance on NIH-Funded Research Resources (<http://sharing.nih.gov>)

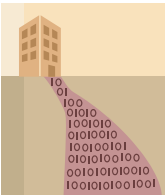
It is NIH policy that the results and accomplishments of the activities that it funds should be made available to the public. PIs and funding recipient institutions are expected to make the results and accomplishments of their activities available to the research community and to the public at large.

Some researchers have incorrectly said sharing of NIH-funded resources didn't apply until after 1999....



NIH...Now and Then

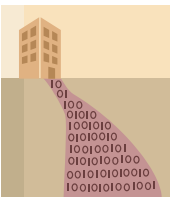
NIH mission to improve public health through research and its longstanding legislative mandate to make available to the public the results of the research activities that it supports and conducts....



The NIEHS and the NIH Overarching Mission and Policies

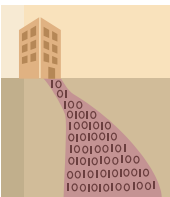
42 USC § 285/. Purpose of Institute

The general purpose of the NIEHS is “the conduct and support of research, training, health information dissemination, and other programs with respect to factors in the environment that affect human health, directly or indirectly.”



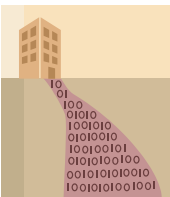
Years of Sharing under NIH Funding: Highlighting Select NIH Sharing Policies

- [NIH Grants Policy Statement \(Availability of Research Results\)](#) (10/2011) - Section of the NIH Grants Policy Statement discussing the availability of research results developed with NIH funding, including publications, data, unique research resources, and intellectual property (inventions and patents).
- [Developing Sponsored Research Agreements \(Considerations for Recipients of NIH Research Grants and Contracts\)](#) (11/1994) - Issues and points to consider in developing sponsored research agreements with commercial entities, where such agreements may include research activities which are fully or partially funded by NIH, in order to assist funding recipients ensure such agreements comply with the requirements of the Bayh-Dole Act and NIH funding agreements while upholding basic principles of academic freedom.



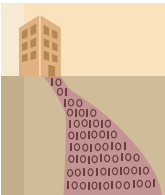
Highlighting Select NIH Sharing Policies

- [Biological Materials Policy \(NIH Procedures for Handling Non-Election of Title to Patentable Biological Materials\)](#) (05/1996) - NIH policy for allowing NIH funding recipients to retain and license biological materials for which patent protection might not be pursued.
- [NIH Research Tools Policy \(Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources\)](#) (12/1999) - Policy designed to provide NIH funding recipients with guidance concerning appropriate terms for disseminating and acquiring unique research resources developed with federal funds, and intended to assist recipients in complying with their obligations under the Bayh-Dole Act and NIH funding policy.



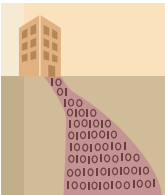
Highlighting Select NIH Sharing Policies

- [NIH Data Sharing Policy \(Final NIH Statement on Sharing Research Data\)](#) (02/2003) - Policy concerning the sharing of research data for funding applications seeking \$500,000 or more in direct costs in any year of the project period (e.g., expects a sharing plan)
- [NIH Model Organism Sharing Policy \(NIH Policy on Sharing of Model Organisms for Biomedical Research\)](#) (05/2004) - Policy concerning the sharing and distributing of model organisms and related research resources generated using NIH funding (e.g., expects a sharing plan).



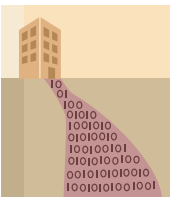
Highlighting Select NIH Sharing Policies

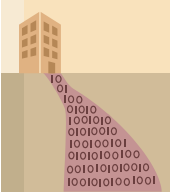
- [NIH Public Access Policy](#) (02/2005) - Policy on Enhancing Public Access to Archived Publications Resulting from NIH-Funded Research.
- [NIH Genome-Wide Association Studies \(GWAS\) Policy \(Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies \(GWAS\)\)](#) (08/2007) - Policy concerning sharing of GWAS data obtained in NIH supported or conducted research.



Compliance with NIH Sharing Policies

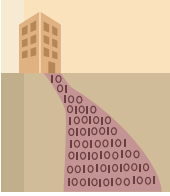
- Who owns what?
 - Grants, cooperative agreements, and contracts are generally awarded to institutions, so institutions are responsible for compliance, but PI and other researchers also need to follow institution's requirements
 - Bayh-Dole Act – Grantee institutions generally have the right to elect title/own subject inventions developed under their NIH funding (but must provide Government Confirmatory License)
 - Applies to inventions
 - If patenting is sought, it should be done appropriately without impeding or “unduly encumbering future research and discovery”
 - Data is generally “owned” by the funded institution
- Sharing certain data may not be possible under limited circumstances, such as, for issues of informed consent, human subjects, etc.
- NIEHS funding must meet its mission and program goals (e.g., how to justify creating a data dissemination center that won't share data?)





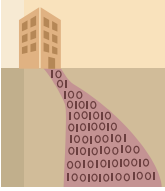
Tools for NIH Sharing

- See NIH Sharing Policy webpage at <http://sharing.nih.gov> or Email at Sharing@nih.gov (Examples of sharing plans (e.g., Data, Model Organisms, etc.) help program and funding applicants review/match acceptable plans)
- [Key Elements to Consider in Preparing a Data Sharing Plan under NIH Extramural Support](#) (12/2009) – This resource document is designed to assist the NIH extramural applicant community in preparing data sharing plans by identifying key elements that should be addressed in the plan.
- [Example Plan addressing Key Elements for a Data Sharing Plan under NIH Extramural Support](#) (08/2010) - This resource document is designed to assist the NIH extramural applicant community in preparing data sharing plans by providing an example that shows how a sharing plan addresses the key elements for a data sharing plan. Easy to follow in order.
- [Data Standards and Common Data Elements Resource Guide](#) (09/2011) - This resource guide document is designed to assist the NIH extramural community in identifying and utilizing certain data standards and common data elements in NIH programs.



Tools for NIH Sharing

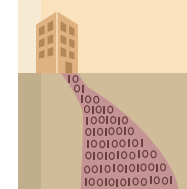
- We know the Why, but Who, What, Where, When, and How?
 - What data will be shared?
 - Who will have access to the data?
 - Where will the data to be shared be located?
 - When will the data be shared?
 - How will researchers locate and access the data?
- Sharing is global, e.g., Wellcome Trust and NIH consistent
 - <http://www.wellcome.ac.uk/About-us/Policy/Policy-and-position-statements/WTX035043.htm>
 - Outputs of the funded research should maximise public benefit
 - Make research data timely and widely available to the research community
 - Share in responsible manner ensuring data can be verified, built upon, and used to advance knowledge and its application to generate improvements in health
 - Researchers should be credited for discoveries and be able to publish first



Tools for NIH Sharing

When sharing is an issue – “Who you gonna call?”

- Program staff of the funding award
- Division of Extramural Inventions & Technology Resources (DEITR), Office of Policy for Extramural Research Administration (OPERA), Office of Extramural Research (**OER**), National Institutes of Health (NIH)
 - Email: Sharing@nih.gov
 - Telephone: (301) 435-1986
 - Facilitate communications among parties and educate them regarding compliance with NIH policies on sharing of resources (data, materials)
 - PI to PI
 - Institution to Institution



- Thank you for your attention -

For any questions on extramural invention reporting, data and resource sharing, or other related extramural intellectual property policy issues:

Contact Information:

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National Institutes of Health (NIH), HHS

6705 Rockledge Drive, Suite 310

Bethesda, Maryland 20817



Websites: <http://sharing.nih.gov>; <http://iEdison.gov>; <http://inventions.nih.gov>

Email: Sharing@nih.gov; Edison@nih.gov; Inventions@nih.gov

DEITR Telephone & iEdison HelpDesk: (301) 435-1986

